IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
WACO DIVISION

W. H. WALL FAMILY HOLDINGS, LLLP, **Plaintiff,** **v.** **STRYKER CORPORATION,** **Defendant.**	**Jury Trial Demanded** **Civil Action No. 6:21-cv-127**

COMPLAINT FOR PATENT INFRINGEMENT

Pursuant to the Federal Rules of Civil Procedure, W. H. Wall Family Holdings, LLLP ("WFH") files its Complaint for Patent Infringement against Defendant Stryker Corporation ("Defendant"), showing this Court as follows.

NATURE OF THE ACTION

1. WFH is the owner by assignment of U.S. Patent No. 6,974,475 (the "'475 Patent"). [A true and correct copy of the '475 Patent is attached hereto as Exhibit 1]. The '475 Patent is a pioneering patent in the field of medical stent technology, with a priority date of December 8, 1987, and a term ending on December 12, 2022.

2. This action arises out of Defendant's infringement of certain claims of the '475 Patent.

THE PARTIES

3. Plaintiff WFH is a limited liability limited partnership organized and existing under the laws of the state of Georgia. WFH's principal place of business is in Stone Mountain, Georgia.

4. Defendant claims to be one of the world's leading medical technology companies, offering products and services in orthopaedics, medical and surgical, and neurotechnology and spine.

5. Upon information and belief, Defendant is a corporation organized and existing under the laws of the state of Michigan, with its principal place of business in Kalamazoo, Michigan. Upon information and belief, Defendant further maintains an office, and regularly does business, in the State of Texas, including maintaining an office in this District.

JURISDICTION AND VENUE

6. This action arises under the patent laws of the United States, including 35 U.S.C. §§271, 281, and 284-285.

7. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§1331 and 1338(a).

8. This Court has personal jurisdiction over Defendant.

9. Venue is proper in this judicial district pursuant to 28 U.S.C. §1400(b).

ATHEROSCLEROSIS AND STENT TECHNOLOGY

10. Atherosclerosis is a buildup of cholesterol and fatty deposits, i.e., plaque, that narrows or blocks blood flow within arteries. Coronary artery disease ("CAD") is a form of atherosclerosis in which plaque narrows or blocks blood flow in the arteries supplying the heart. Similarly, peripheral artery disease ("PAD") is a form of atherosclerosis in which plaque narrows or blocks blood flow in arteries not leading to heart, such as those leading to an arm or leg.

11. These blockages, or atherosclerotic lesions, are frequently treated with percutaneous transluminal intervention (PTI).

12. Initial PTI procedures included coronary angioplasty, first performed by Andreas Greuntzig in 1977.

13. During an angioplasty procedure, a specially designed catheter with a tiny balloon is carefully guided through the artery to the blockage, then inflated to widen the opening and increase blood flow within the artery. Although largely effective, angioplasty occasionally resulted in a number of adverse effects, including damage to the artery or post-operative closure of the artery.

14. Over time, doctors have recognized that these adverse effects from treating atherosclerosis with angioplasty alone may be mitigated by using stents in conjunction with angioplasty. A stent is a wire mesh tube or "scaffold" that is permanently implanted in the artery to keep the artery open and can be combined

with angioplasty to treat atherosclerosis. The stent helps support the inner wall of the artery following the PTI procedure.

15. Generally speaking, there are two types of stents: (1) balloon-expandable stents and (2) self-expandable stents.

16. Balloon-expandable stents are biased in a collapsed position and the surgeon uses an angioplasty balloon to expand and set the stent within the arterial segment containing the blockage. With balloon-expandable stents, a balloon is inflated to compress the plaque that has built up inside the artery against the artery's wall. The stent, which was carried on the deflated balloon, expands when the balloon expands, and is pushed into place in the artery. The balloon is then deflated and removed along with the catheter, leaving the stent in place.

17. Self-expandable stents are biased in an expanded position but are constrained within a delivery mechanism until placement, when the surgeon removes the constraining device allowing expansion of the stent. With self-expandable stents, the surgeon may also utilize balloon angioplasty to expand the artery prior to stent placement.

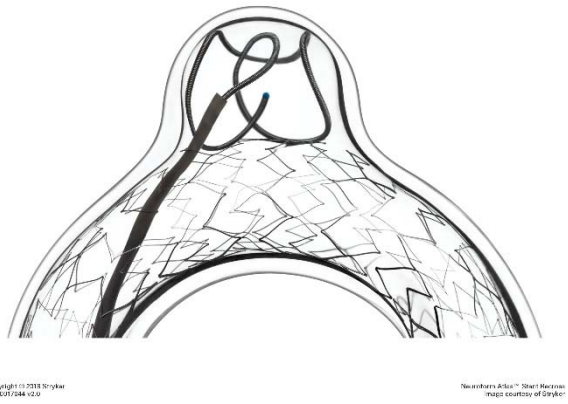
OTHER USES OF STENT TECHNOLOGY

18. Other lumens in the human body may also become obstructed through either malignant or benign growths or injury, including bile ducts.

19. Biliary stenting is a procedure widely used to remedy biliary obstructions. A biliary stent is a small, expandable mesh tube or "scaffold" usually made of metal or plastic that is placed at the location of the obstruction and expanded to provide a passage through the obstruction to increase the flow of bile through the duct. The stent helps support the inner wall of the lumen.

20. Other uses of stents also include the treatment of certain aneurysms. An aneurysm is a weakening in the wall of a lumen, such as an artery or vein, that causes the lumen to bulge and risk rupture. For instance, wide-necked aneurysms may be treated by the placement of one or more coils into the aneurysm, causing clotting of blood within the aneurysm to and the reduction of the likelihood of rupture. In certain cases, the coils are further supported by a stent to avoid the coils' displacing from the aneurysm and blocking the lumen.

21. Treatment of wide-necked aneurysms through a stent-supported embolization coil is similar to the treatment of cardiovascular occlusions to the extent that, in both treatments, a surgeon places a stent in the affected area of the lumen via a catheter guided to the area. The treatment of wide-necked aneurysms include an additional step of deploying one or more embolization coils into the aneurysm after placement of the stent, as shown below:



THE '475 PATENT

22. In 1981, while he was working as a visiting clinical professor at Emory Dental School, Dr. Wall became acquainted with Dr. Greuntzig, who had recently joined the Emory faculty. Dr. Wall studied the balloon angioplasty therapy pioneered by Dr. Greuntzig and concluded that arterial blockage would likely return in patients—a condition referred to as restenosis. Dr. Wall considered this issue and began working on ideas to address this problem. Initially, he tried to develop an ultrasound method to remove the blockage.

23. After experimenting with this idea, Dr. Wall concluded that this method was not a viable solution. On or about October 15, 1984, he conceived the invention of inserting a sleeve into an artery following an angioplasty procedure. The sleeve would then effectively hold open the artery and prevent restenosis. Dr. Wall filed a disclosure document with the USPTO in December 1984, and filed patent application no. 07/129,834 (the "'834 Application") on December 8, 1987.

24. The ’834 Application duly issued as the ’475 Patent on December 13, 2005.

25. WFH is the owner by assignment of all rights in the ’475 Patent.

26. The ’475 Patent relates generally to a prosthesis that can be inserted into a bodily lumen while in a collapsed position, and then expanded in order to prevent restenosis in the lumen. WFH has the right to enforce the ’475 Patent and to recover all damages available under law.

27. As an example, Claim 39 of the ’475 Patent provides:

> 39. A stent for placement into a narrowed opening of a lumen of the human body and for maintaining at least a minimum opening within the lumen, said stent comprising:
>
> a radially collapsible sleeve formed in a mesh and a coating applied thereto,
>
> said sleeve defining a plurality of openings throughout the mesh to allow tissue to grow therethrough, and
>
> said mesh being biased toward either its collapsed position or its expanded position.

28. The ’475 Patent, and Dr. Wall’s invention described therein, have been the subject of numerous articles, including a 2006 article in the Wall Street Journal, entitled “Will Stent Makers Fight Dentist’s Patent Tooth and Nail?”

29. In 2008, Plaintiff's predecessor-in-interest sued Boston Scientific Corp. in a well-publicized action, asserting infringement of '475 Patent by various stent products of Boston Scientific. This parties settled this litigation on confidential terms.

30. Upon information and belief, Plaintiff caused a notice to be sent to Defendant regarding the existence of the '475 Patent and inviting Defendant to enter into negotiations regarding a license in 2011. Plaintiff did not receive a response to this letter.

31. Upon information and belief, Defendant then acquired certain neurovascular division assets and related facilities of Boston Scientific in late 2011, including its Neuroform EZ and Wingspan stents, but not the Neuroform Atlas stent that Defendant developed after this transaction.

32. Defendant has been on notice of the '475 Patent and Defendant's infringement of the '475 Patent since at least 2011.

DEFENDANT'S NEUROFORM ATLAS STENT SYSTEM

33. In May 2019, the U.S. Food and Drug Administration (the "FDA") in issued a Pre-Market Approval for the Neuroform Atlas Stent System (the "Accused Product"), stating the product was approved for use with neurovascular embolization coils in the anterior circulation of the neurovasculature for the endovascular treatment of patients ≥ 18 years of age with saccular wide-necked

(neck width ≥ 4 mm or a dome-to-neck ratio of < 2) intracranial aneurysms arising from a parent vessel with a diameter of ≥ 2.0 mm and ≤ 4.5 mm.

[May 16, 2019, Pre-Market Approval for the Neuroform Atlas Stent System, a copy of which is attached hereto as Exhibit 2, at p. 1].

34. The Neuroform Atlas Stent System comprises "[a] self-expanding, open-cell, nitinol stent with three radiopaque markerbands on each end (proximal and distal) and four interconnects between the central stent segments, designed to provide support for the coil mass within the aneurysm and minimize stent deflection."

[Stryker Neurovascular, NEUROFORM ATLAS STENT SYSTEM DIRECTIONS FOR USE (the "Atlas DFUs"), p. 2, a true and correct copy of which is attached hereto as Exhibit 3].

35. The Accused Product further comprises a radially collapsible sleeve formed in a mesh with, upon information and belief, a coating applied thereto through, e.g., electropolishing.

36. The Accused Product further comprises a sleeve defining a plurality of openings throughout the mesh to allow tissue to grow therethrough.

37. The Atlas DFUs further explain that a delivery catheter is used to position the Accused Product in a lumen. [Ex. 3, pp. 27-30]. Once properly positioned, the Atlas Stent is expanded by removal of a constricting covering

sheath. [Ex. 3, p. 30]. Once fully expanded, the deployment of the stent is completed by removal of the delivery catheter. [Ex. 3, p. 30].

38. The Accused Product thus further comprises a mesh stent that is biased towards its open position, but constrained within a sheath until allowed to expand after placement by the surgeon.

39. WFH has satisfied all statutory obligations required to collect pre-filing damages for the full period allowed by law for infringement of the ’475 Patent.

40. All other conditions precedent to the assertion of the claims herein have been satisfied or waived.

COUNT I
DIRECT INFRINGEMENT—’475 PATENT

41. WFH incorporates by reference as if fully set forth herein its averments in Paragraphs 1-40, above.

42. As set forth above, the Accused Product comprises, literally or through the doctrine of equivalents, each limitation of at least Claim 39 of the ’475 Patent.

43. Defendant has manufactured, sold and offered for sale the Accused Product within the U.S. since at least May 2019, in violation of 35 U.S.C. §271, *et seq.*

44. On information and belief, including the allegations above showing knowledge and intent, despite having knowledge of the ’475 patent and knowledge that it is directly infringing one or more claims of the ’475 patent, Defendant has nevertheless continued its infringing conduct and disregarded an objectively high likelihood of infringement. Defendant’s infringing activities relative to the ’475 patent have been, and continue to be, willful, wanton, malicious, in bad-faith, deliberate, consciously wrongful, flagrant, characteristic of a pirate, and an egregious case of misconduct beyond typical.

45. WFH has been, and continues to be, damaged by Defendant’s infringement of the ’475 Patent, in an amount not less than a reasonable royalty, together with interests and costs as fixed by this Court pursuant to 35 U.S.C. §284.

46. WFH is entitled to recover from Defendant the damages sustained by WFH as a result of Defendant’s wrongful acts in an amount subject to proof at trial, which, by law, cannot be less than a reasonable royalty, together with interest and costs as fixed by this Court.

47. WFH has incurred and will incur attorneys’ fees, costs, and expenses in the prosecution of this action. The circumstances of this dispute may give rise to an exceptional case within the meaning of 35 U.S.C. § 285, and WFH is entitled to recover its reasonable and necessary attorneys’ fees, costs, and expenses.

JURY DEMAND

48. WFH hereby requests a trial by jury pursuant to Rule 38 of the Federal Rules of Civil Procedure.

PRAYER FOR RELIEF

49. WFH respectfully requests that the Court find in its favor and against Defendant, entering a judgment in favor of WFH and granting the following relief:

a) Finding that Defendant has infringed the ’475 Patent as alleged herein;

b) Requiring an accounting of all damages sustained by WFH as a result of the acts of infringement by Defendant;

c) A preliminary and permanent injunction against Defendant, its subsidiaries, or anyone acting on its behalf from making, using, selling, offering to sell, or importing any products that infringe the ’475 Patent and any other injunctive relief the Court deems just and equitable;

d) Awarding to WFH damages under 35 U.S.C. §284, including not less than a reasonable royalty and up to treble damages;

e) Requiring Defendant to pay WFH pre-judgment and post-judgment interest on the damages awarded;

f) Awarding to WFH the statutory costs of this action;

g) Finding this to be an exceptional case and requiring Defendant to pay to WFH its attorneys' fees and non-statutory costs incurred in this action under 35 U.S.C. §285; and

h) Awarding WFH such other and further relief as this Court deems just and appropriate, premises considered.

This 5th day of February, 2021.

Respectfully submitted,

LOCKE LORD LLP

By:*/s/ Bryan G. Harrison*

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